Multiplex Polymerase Chain Reaction (PCR) Instrument (Film Array 2.0)

ITEM NUMBER	DESCRIPTION OF SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Film Array 2.0 Instrument BIOFIRE PART NUMBER: FLM2-ASY-0001 OR EQUAL	3.00	EA	_____	_____
0002	Computer Kit BIOFIRE PART NUMBER: FLM2-ASY-0003 OR EQUAL	1.00	EA	_____	_____
0003	Duo Rack BIOFIRE PART NUMBER: FLM2-ASY-0005 OR EQUAL	2.00	EA	_____	_____
0004	Printer Kit BIOFIRE PART NUMBER: FLM2-ASY-0008 OR EQUAL	1.00	EA	_____	_____
				GRAND TOTAL	_____

DESCRIPTION

The purpose of this agreement is for the Contractor to provide the Orlando VA Clinical Microbiology Lab with 3 multiplex PCR instruments which shall have the capability of identifying the nucleic acid of targeted pathogens in positive blood culture broth, upper respiratory specimens, and gastrointestinal specimens in accordance with the terms and conditions stated herein. The instrument shall be able to integrate sample preparation, amplification, detection and analysis as described below and meet the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI). The instrument must be approved by the Food and Drug Administration (FDA). The Contractor shall propose the suggested/recommended equipment/reagents that meet the requirements of the facility.

SALIENT CHARACTERISTICS

1. GENERAL REQUIREMENTS (APPLICABLE TO ALL EQUIPMENT): Each model of multiplex PCR analyzer offered shall comply with all general requirements stated herein. Each Contractor shall submit as part of their offer, technical data or descriptive literature to ascertain that the equipment offered meets the requirements outlined below.

a. The Contractor shall provide FDA approved, multiplex PCR analyzers. Remanufactured or discontinued models are unacceptable for this agreement.

b. The Contractor shall state the failure mean time (between failure and mean time to repair) for each piece of equipment offered. Emergency replacement of equipment shall be provided by the Contractor.

2. MULTIPLEX PCR SPECIAL REQUIREMENTS:

a. **GENERAL REQUIREMENTS:**

(1) The system shall provide integrated sample preparation, amplification, detection, and analysis in one process that delivers results in an hour with minimal hands-on time required.

(2) The system will be capable of processing positive blood culture broth, respiratory specimens and gastrointestinal specimens to detect the nucleic acid of significant bacterial, viral, parasitological, and fungal pathogens from these specimens.

(3) The vendor shall provide hardware/software upgrades necessary to maintaining the integrity of the system at no additional charge to the government. These must be provided as they become available and as they are being offered to commercial customers.

(4) The system will have the ability to make efficient use of endpoint melting curve data which permits automatic generation of a result for each target. The system will use pre-filled pouches, no sharps and operator will have no need to handle or transfer tubes once the system is loaded.

(5) Ancillary Equipment and Supplies: The Contractor shall provide, install and maintain, as indicated, any and all ancillary support equipment, consumables/supplies, parts and accessories necessary to fully operate the multiplex PCR analyzer(s) as defined in these specifications, e.g., cabinetry to support/house the analyzer (if necessary), universal interface equipment,

Uninterruptible Power Supply (UPS) capable of supporting the full scope of equipment operation with a built-in line conditioner, for each proposed analyzer. The Contractor shall include all ancillary components that are customarily sold or provided with the model of equipment proposed, e.g. starter kits, tables/stands, etc.

(6) Training: The Contractor shall provide training at the time of installation to include training on the operation of the system, data manipulation, preventative maintenance and basic trouble shooting and repair for 2 key operators. Any training program that involves off-site travel shall include the cost of airfare, room and board for each participant. A training or competency checklist shall be provided by the Contractor.

(7) Site Preparation: Site preparation specifications shall be furnished in writing by the Contractor as a part of the equipment quote. These specifications shall be in such detail as to ensure that the equipment to be installed shall operate efficiently and conform to the manufacturer's claimed specifications thereby not creating a safety hazard.

(8) Implementation and Transition: The Contractor shall provide with its quotation a transitioning plan for the complete transition of all services under the awarded agreement including installation and training of personnel, transition of all testing materials, reagents and supplies, etc., performance of all correlations and validations. This transition shall be completed no later than 30 days after the award of the agreement. This timeline is based on a reasonable attempt of the Contractor to complete all of the necessary implementation requirements within the stated timeframe.

(9) Comparison and Validation of Analyzer: If the vendor is supplying an equal product, the Contractor shall assist, to the satisfaction of the Government, at no cost to the Government, all comparison and validation studies to include any materials and reagents needed for such correlation. The Contractor shall perform all of the statistical analysis and report data in an organized, clearly comprehensible format. This process shall be completed within two weeks of installation of the analyzer and shall be consistent with current CLSI (formerly NCCLS) and related documents, CAP Standards and Federal Regulations.

(10) The vendor shall provide a copy of operating procedures in Clinical and Laboratory Standards Institute (CLSI) digital format at time of installation using software compatible with VA (Microsoft Office WORD).

b. **TECHNICAL REQUIREMENTS:**

(1). Bar-code System. The system shall support bar-code recognition with a simple 4-step operating procedure.

(2) Data Management System.

(a) Shall be able to analyze and report results in a simple and easy to read format.

(b) Shall provide automated qualitative data analysis in Windows-based software.

(c) Shall be capable of maintaining all data for up to 1 hour in the event of normal electrical power interruptions via battery backup.

(d) Shall have a built-in quality control program to regularly monitor performance of vital components.

(3) Multiplex PCR Panels.

(a) The Respiratory Panel shall be able to identify 20 targets, both viral and bacterial common pathogens.

(b) The Gastrointestinal Panel shall be able to identify common gastrointestinal pathogens including viruses, bacteria, and parasites that cause infectious diarrhea.

(c) The Blood Culture Identification Panel shall be able to identify 27 targets including 24 pathogens (bacterial and fungal), and 3 antibiotic resistance genes associated with bloodstream infections.

(d) The panels shall not require the use of any sharps for sample/reagent transfer.

(c) The panels shall be approved for positive blood culture broth, sputum, and stool specimens.

(5) Safety: The system must have sufficient safety features to avoid unnecessary exposure to bio-hazardous and chemical materials. The exposure to and the volume of bio-hazardous and chemical material generated by the equipment must be minimal and require a minimum amount of handling.

3. Progress and Compliance: The system must perform multiplex PCR preparation, amplification, detection, and analysis as advertised, and meet the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI).